

Rec'd PCT/PTO 3 JAN 2006

10/529393

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit:
Zi-Hua JIANG	)	
	)	Examiner:
Serial No.: 10/529,393	)	Washington, D.C.
	)	
IA Filed: September 29, 2003	)	January 31, 2006
	)	
For: GLYCOSYLCERAMIDE ANALOGUES)		Docket No.: GANDHILA

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii"

below). See 37 CFR 1.97(c).

[ ] i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[ ] ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. \_\_\_\_\_).

[ ] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed (check no. \_\_\_\_\_). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[ ] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR \$1.129(a). Pursuant to MPEP \$706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR \$1.97(b)

and considered without the petition and petition fee required by 1.97(d).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[ ] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[ ] A. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance

with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

☐ 3. Documents \_\_\_\_\_ are not in the English language. In accordance with 1.98(c), Applicants state:

- ☐ documents \_\_\_\_\_ already contain an English language abstract, summary or claim set.
- ☐ a publicly available abstract is attached to each of documents \_\_\_\_\_, and the source of each abstract is indicated thereon.
- ☐ documents \_\_\_\_\_ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

- ☐ applicants have prepared an English translation of

at least the pertinent portions of documents \_\_\_\_\_, and copies are attached.

[ ] A concise explanation of the relevance of documents \_\_\_\_\_ is found in the attached search report from the \_\_\_\_\_ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] A concise explanation of the relevance of documents \_\_\_\_\_ is set forth as follows:  
[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

[insert other information]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

7. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 3

**Complete if Known**

Application Number	10/529,393
Filing Date	September 29, 2003
First Named Inventor	Zi-Hua JIANG
Group Art Unit	
Examiner Name	
Attorney Docket Number	GANDHI1A

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/E.P./	/AA	US-6,569,889	05-27-2003	SHAYMAN et al	
/E.P./	/AB	US-6,103,883	08-15-2000	LINGWOOD et al	
/E.P./	/AC	US-6,531,453	03-11-2003	TANIGUCHI et al	
/E.P./	/AD	US-6,555,372	04-29-2003	MOTOKI	
/E.P./	/AE	US-6,136,790	10-24-2000	TOEPFER et al	
/E.P./	/AF	US-6,417,167	07-09-2002	MARUYAMA et al	
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Number Country Code* Number* Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>

**NON PATENT LITERATURE DOCUMENTS /OTHER INFORMATION**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/E.P./	AG	HANESSION, STEPHEN et al "Synthesis of chemically and functionally diverse scaffolds from pentaerythritol" Can.J.Chem. 74 (1996) pp:1731-1737	
/E.P./	AH	MIYAMOTO, KATSUICHI et al "A synthetic glycolipid prevents autoimmune encephalomyelitis by inducing T <sub>H</sub> 2 bias of natural killer T cells" Nature, Vol. 413 (October 2001) pp:531-534	
/E.P./	AI	BROSSAY, LAURENT "Cutting Edge: Structural Requirements for Galactosylceramide Recognition by CD1-Restricted NK T Cells" The Journal of Immunology (1998) pp:5124-5128	
/E.P./	AJ	COSTANTINO, VALERIA et al "Glycolipids from Sponges. IV. Immunomodulating Glycosyl Ceramides from the Marine Sponge Agelas Dispar" Tetrahedron, Vol 52, No. 5, pp:1573-1578	
/E.P./	AK	GONZALEZ-ASEGUINOLAZA, GLORIA et al "Natural Killer T Cell Ligand $\alpha$ -Galactosylceramide Enhances Protective Immunity Induced by Malaria Vaccines" J. Exp. Med. Vol 195 No. 5 (March 2002) pp617-624	
/E.P./	AL	NATORI, TAKENORI et al "Agelasphins, novel antitumor and immunostimulatory cerebroside from the marine sponge Agelas mauritanicus" Tetrahedron, Vol 50, No. 9 (1994) pp:2771-2784	

Examiner Signature	/Elli Peseelev/	Date Considered	12/03/2008
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Attorney Docket Number	GANDHI1A

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	† <sup>2</sup>
/E.P./	AM	NEIL E. et al "Towards the nonstick egg-designing fluoros proteins" Chemistry & Biology (2000) Vol. 7, No. 7 PP153-157	
/E.P./	AN	LINDHORST, THIBSE K et al "Cluster Mannosides as Inhibitors of Type 1 Fimbriae-Mediated Adhesion of Escherichia coli: Pentaerythritol Derivatives as Scaffolds" Eur.J.Org. Chem (2000) pp: 2027-2034	
/E.P./	AO	CLARY, LAURENCE et al "Synthesis of Single- and Double-chain Fluorocarbon and Hydrocarbon $\beta$ -linked Galactose Amphiphiles derived from Serine" Tetrahedron Letters, (1995) Vol. 36, No. 4, pp:539-542	
/E.P./	AP	FAROUX-CORLAY, BARBARA et al "Synthesis of single- and double-chain fluorocarbon and hydrocarbon galactosyl amphiphiles and their anti-HIV-1 activity" Carbohydrate Research 327 (2000) pp:223-260	
/E.P./	AQ	SCHMIDT, MATTHIAS et al "Synthesis of Glycolipid Clusters with Pentaerythritol Cores and Different Ethyleneoxy-Spaced Mannose Residues as Terminal Carbohydrates" Eur.J.Org Chem. (2002) pp:669-674	
/E.P./	AR	CHENG, XIAO HONG "Molecular Design of Liquid-Crystalline Block Molecules: Semifluorinated Pentaerythritol Tetrabenzoates Exhibiting Lamellar, Columnar, and Cubic Mesophases" Agnew. Chem. Int.Ed. (2000) Vol.39, No.3 pp:5925-595	
/E.P./	AS	ARMSPACH, DOMINIQUE et al "Boron-rich metallodendrimers-mix-and-match assembly of multifunctional metallosupramolecules" Chem. Commun., (1996) pp:1823-1824	
/E.P./	AT	TOEPFER, ALEXANDER et al "Synthesis of Novel Mimetics of the Sialyl Lewis X Determinant" Tetrahedron Letters, Vol 36, No. 50, (1995) pp:9161-9164	
/E.P./	AU	WORLD, RALF et al "Synthesis of New Liquid Phase Carriers for Use in Large Scale Oligonucleotide Synthesis in Solution" Tetrahedron 55 (1999) pp:2941-2956	
/E.P./	AV	KUZDZAI, SCOTT A. "Dendrimer Electrokinetic Capillary Chromatography: Unimolecular Micellar Behaviour of Carboxylic Acid Terminated Cascade Macromolecules" J.Chem.Soc. Chem Commun. (1994) pp:2139-2140	
/E.P./	AW	NIEMZ, ANGELIKA et al "Self-Association and Membrane-Binding Behavior of Melittins Containing Trifluoroisoleucine" J.Am Chem.Soc. (2001), 123, pp:7407-7413	

Examiner  
Signature

/Elli Peselev/

Date  
Considered

12/03/2008

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



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Sheet 3 of 3

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/E.P./	AX	AGUILERA, BEGONA et al "Novel Disaccharide Inhibitors of Human Glioma Cell Division" J.Med.Chem. (1998) 41, pp.4599-4606	
/E.P./	AY	MORITA, MASAHIRO et al "Structure-Activity Relationship of $\alpha$ -Galactosylceramides against B16-Bearing Mice" J.Med.Chem. (1995) 38, pp2176-2187	
/E.P./	AZ	FAROUX-CORLAY, BARBARA et al "Amphiphilic Anionic Analogues of Galactosylceramide: Synthesis, Anti-HIV-1 Activity, and gp120 Binding" J.Med.Chem (2001) 44, pp: 2188-2203	
/E.P./	BA	UCHIMURA, AKIRA et al "Immunostimulatory Activities of Monoglucosylated $\alpha$ -D-Pyranosylceramides" Bioorganic and Medicinal Chemistry, (1997)Vol. 5 (12), pp: 2245-2249	
/E.P./	BB	SHARIF, SHAYAN et al "Activation of natural killer T cells by $\alpha$ -galactosylceramide treatment prevents the onset and recurrences of autoimmune Type 1 diabetes" Nature Medicine, (September 2001) Vol. 7, No. 9, pp:1057-1062	
/E.P./	BC	GONZALEZ-ASEGUINOLAZA et al "G-Galactosylceramide-activated V $\alpha$ 14 natural killer T cells mediate protection against murine malaria" PNAS (July 2000) vol. 97, No. 15, pp.8461-8466	
/E.P./	BD	KAWANO, TETSU et al "CD1d-Restricted and TCR-Mediated Activation of V $\alpha$ 14 NKT Cells by Glycosylceramides" Science, (November 1997) Vol. 278, pp:1626-1629	
/E.P./	BE	UCHIMURA, AKIRA et al "Immunostimulatory Activities of Mono- or Diglycosylated $\alpha$ -Galactosylceramides" Bioorganics and Medicinal Chemistry, (1997) Vol. 5, No. 7, pp 1447-1452	
/E.P./	BF	COSTANTINO, VALERIA et al "Glycolipids from Sponges. VII. Simplexides, Novel Immunosuppressive Glycolipids from the Caribbean Sponge Plakortis simplex" Bioorganic & Medicinal Chemistry Letters 9 (1999) pp: 271-276	

Examiner Signature	/Elli Peselev/	Date Considered	12/03/2008
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